



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0434; FRL-9636-01-OCSP]

Teflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide teflubenzuron in or on grape and grape, raisin. There is no U.S. registration associated with these tolerances.

BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0434, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744.

Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director,

Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at

<https://www.ecfr.gov/current/title-40>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0434 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing

Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0434, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 24, 2021 (86 FR 47275) (FRL-8792-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8874) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.687 be amended by establishing tolerances for residues of the insecticide teflubenzuron, (*N*-[[[(3,5-dichloro-2,4-difluorophenyl)amino]carbonyl]-2,6-difluorobenzamide), in or on grape at 0.7 parts per million (ppm) and grape, raisin at 0.9 ppm. That document referenced a summary of the petition

prepared by BASF Corporation, which is available in docket ID number EPA-HQ-OPP-2021-0434 in <https://www.regulations.gov>. No substantive public comments were received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for teflubenzuron including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with teflubenzuron follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for teflubenzuron in which EPA

concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to teflubenzuron and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of teflubenzuron, see Unit III.A of the teflubenzuron tolerance rulemaking published in the *Federal Register* of October 30, 2015 (80 FR 66805) (FRL-9933-25).

Toxicological Points of Departure/Levels of Concern. For a discussion of the Toxicological Points of Departure/Levels of Concern used for the safety assessment of teflubenzuron, see Unit III.B of the October 30, 2015, rulemaking.

Exposure Assessment. Much of the exposure assessment for teflubenzuron remains unchanged from the discussion in Unit III.C of the October 30, 2015, rulemaking, except as described below.

The current exposure assessment incorporates the additional dietary exposure from this petitioned-for tolerances. Because this action establishes tolerances for residues of teflubenzuron in or on imported commodities for which there are no associated U.S. registrations, dietary exposure (food only) is the only anticipated exposure pathway. There are no domestic agricultural or residential uses registered or proposed for teflubenzuron that would result in drinking water or residential exposures. This tolerance petition does not warrant an occupational handler exposure assessment because the petition is for import tolerances without a U.S. registration. There are no short- or intermediate-term exposures from the use of teflubenzuron. An acute risk assessment was not performed because there were no toxicological effects attributable to a single dose identified.

The unrefined chronic dietary (food only) exposure estimates represent the aggregate exposure assessment and assumed that teflubenzuron residues are present in all commodities at tolerance levels and that 100% of all crops are treated. Empirical processing factors of 0.08 for

apple juice and 0.04 for orange juice were incorporated into the dietary exposure model and the Agency's 2018 default processing factors were used to estimate residues in other processed commodities. The Agency's approach for assessing these factors is discussed in detail in the document titled "Chronic Dietary (Food Only) Exposure and Risk Assessment for the Proposed Tolerances Without a U.S. Registration for Residues in/on Grapes." in docket ID number EPA-HQ-OPP-2021-0434.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D of the October 30, 2015, rulemaking.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

An endpoint of concern attributable to a single dose was not identified; therefore, an acute dietary assessment was not performed. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD for the U.S. general population and all population subgroups. The most highly exposed population subgroup is children 1-2 years old with an estimated risk of 48% of the cPAD.

In accordance with the EPA's "Final Guidelines for Carcinogen Risk Assessment" (March 2005), the Cancer Assessment Review Committee (CARC) classified teflubenzuron as "Suggestive Evidence of Carcinogenic Potential" based on the presence of rare liver tumors in male mice only. The Agency has determined that quantification of risk using a non-linear approach (i.e., reference dose [RfD]) will adequately account for all chronic toxicity, including

carcinogenicity, that could result from exposure to teflubenzuron. Therefore, the chronic dietary risks, which are not of concern, are considered protective of both non-cancer and cancer effects.

Determination of Safety. Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to teflubenzuron residues. More detailed information about the Agency's analysis can be found at <https://www.regulations.gov> in the document titled "Chronic Dietary (Food Only) Exposure and Risk Assessment for the Proposed Tolerances Without a U.S. Registration for Residues in/on Grapes." This document can be found in docket ID number EPA-HQ-OPP-2021-0434.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available to enforce the petitioned-for tolerances for residues of teflubenzuron in/on crop commodities. Samples were analyzed for residues of teflubenzuron using a high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), SOP-PA.0250. Acceptable concurrent recoveries were reported for samples of grape fortified with teflubenzuron at 0.01-1.0 ppm, thus validating the method. The limit of quantitation (LOQ; determined as the lowest level of method validation, LLMV) was 0.01 ppm. The estimated LOD (limit of detection) was 20% of the LOQ or 0.002 ppm.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755-5350; telephone number: (410) 305-2905. email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The U.S. tolerance level for grape residues established in this action is harmonized with Codex. There are no established Canadian or Mexican MRLs for residues of teflubenzuron on grape. Additionally, there are no established Codex, Canadian, or Mexican MRLs for residues of teflubenzuron on grape, raisin.

C. Revisions to Petitioned-For Tolerances

Based upon the submitted data, no revisions to the petitioned-for tolerances proposed for residues in/on grape and grape, raisin are needed.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide teflubenzuron, (*N*-[[[3,5-dichloro-2,4-difluorophenyl]amino]carbonyl]-2,6-difluorobenzamide), in or on grape at 0.7 ppm; and grape, raisin, at 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does

not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 24, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.687:

a. Amend paragraph (a)(1) by:

i. Adding a table heading;

ii. Adding the commodities “Grape” and “Grape, raisin” to the table in alphabetical order;

and

iii. Revising footnote 1.

b. Add a reserved paragraph (a)(2).

c. Remove and reserve paragraphs (b), (c), and (d).

The additions and revision read as follows:

§ 180.687 Teflubenzuron; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * *	* * *
Grape ¹	0.7
Grape, raisin ¹	0.9
* * *	* * *

¹ Tolerance without U.S. registration.

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